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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/507,146	02/18/00	NEWMAN W	L0559/7001(E

HM12/1107

ELIZABETH R. PLUMER
WOLF GREENFIELD & SACKS PC
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON MA 02210

EXAMINER	
CANELLA,K	
ART UNIT	PAPER NUMBER
1642	13

DATE MAILED: 11/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/507,146	Newman et al
Examiner	**Art Unit**
Karen Canella	1642

-- Th MAILING DATE of this communication appears on th cover she t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 *months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 6, 7, 10, 11, 15, 20-24, and 41-55* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 6, 7, 10, 11, 15, 20-24, and 41-55* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

2. Claims 27 and 56-58 have been canceled. Claims 1, 10 and 11 have been amended. Claims 1, 6, 7, 10, 11, 15, 20-24, 34 and 41-55 are pending and under consideration.

3. The rejection of claims 1 and 21 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a complex comprising an anti-biotin antibody and biotinylated eosin and a complex comprising an anti-biotin antibody and biotinylated ITAC, does not reasonably provide enablement for complexes consisting of any other biotinylated conjugate, is withdrawn.

4. The rejection of claims 6, 7, 10, 11, 15, 20, 22-24, 34 and 41-55 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a complex comprising an anti-biotin antibody and biotinylated eosin and a complex comprising an anti-biotin antibody and biotinylated ITAC in an experimental protocol of lymphocyte recruitment to the peritoneum, does not reasonably provide enablement for complexes consisting of any other biotinylated conjugate, is maintained for reasons of record. Applicant has provided abstracts from numerous articles to demonstrate the use of G-protein coupled receptors and ligands as therapeutic agents. This has been considered but not found persuasive as the instant invention as taught by the specification is not chemokines per se but pharmaceutical agents comprising an anti-biotin antibody complexed to biotinylated chemokines administered in vivo, wherein the antibody complex is released upon reaction with endogenous or administered biotin to free the biologically active chemokine fusion protein. The specification has not provided any teachings to enable one of skill in the art to use the broadly claimed complexes in the treatment of specific disease states

as the specification has not demonstrated the adequate delivery of the complex and the release of the active chemokine to remedy an actual disease state in an organ or the blood stream vs a model of experimental lymphocyte recruitment to the peritoneum. Further, claims 22-24 are drawn to antibodies having a dual specificity thus binding biotin and another antigen. Claims 23 and 24 specify a tumor cell antigen and a viral antigen. However, there is no teaching in the specification to explain how an antibody designed to release biotin in vivo will persist as a complex long enough to deliver the biotinylated chemokine to the site of the tumor or viral antigen.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVico et al (US 6,214,540) in view of Mehta et al (US 6,303,325). Claim 1 is drawn to a composition comprising a complex of a biotinylated chemokine and a anti-biotin antibody. Claim 21 embodies a diagnostic reagent attached to the anti-biotin antibody. DeVico et al teach a

biotinylated chemokine and a method of labeling or detecting of a biotinylated chemokine by means of an antibody complex in place of avidin FITC. Devico et al do not specifically teach the formation of complex of biotinylated chemokine and an anti-biotin antibody in place of the avidin FITC. Mehta et al teach an anti-biotin antibody for the general detection of biotin. It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to use the specific anti-biotin antibody for the formation of a complex with the biotinylated chemokine. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Mehta et al on the utility of the anti-biotin antibody in the detection of conjugated biotin.

8. All other rejections and objections as stated in Paper No. 10 are withdrawn.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
November 5, 2001